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Appin. No. 09/981,483 Amdt. dated March 19, 2004 Reply to Office action dated Jan. 16, 2004 PATENT Customer No. 22,878 Attorney Docket No. 10003016 Finnegan Ref. No.: 07896.0058-00000

#### REMARKS / ARGUMENTS

In response to the Office action dated January 16, 2004 ("OA"), Applicant respectfully requests the Office to enter the following amendments and consider the following remarks. By this response, claims 1, 6, 7, 11, 12, 21-23 and 32 have been amended, and claim 10 has been canceled without prejudice. With respect to the pending claims, claims 1-9 and 11-43 remain pending in this application, and new claims 44-81 have been added. Authorization is hereby given to charge any fees (e.g., extension fees) associated with this response to Deposit Account No. 50-1078.

In the Office action, the Examiner: objected to Fig. 2 because a reference sign was not referenced in the written description, rejected claims 1-5, 8-10, 12-20, 22-26, 29 and 32-39 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,772,586 to Heinonen et al. ("Heinonen"), rejected claims 27 and 28 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Heinonen, and rejected claims 30, 31, 40 and 41 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Heinonen further in view of U.S. Published Patent Application No. 2003/0083685A1 to Freeman et al. ("Freeman"). Claims 21, 42 and 43 were indicated as being allowable, as were claims 6, 7, and 11, if rewritten in independent form.

Applicant submits that the proposed amendments of claims 1, 6, 7, 11, 12, 21-23 and 32 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined.

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Applicant addresses the new arguments as to the application of the art against Applicant's invention, and respectfully submits the pending claims' allowability, as follows.

# **Drawings**

The Examiner has objected to Figure 2 under 37 C.F.R. § 1.84(p)(5) on the basis that it includes reference sign "200," which is not mentioned in the description. See OA at page 2, ¶1. Applicant has amended paragraph [027] of the written description (which begins at page 8, line 18) to recite that reference sign 200 in Fig. 2 refers to a cut-away view of a portable medical analyzer as stated earlier in the brief description of the drawings. See paragraph [012]. Applicant submits that no new matter has been added via this amendment.

### Claim Rejections - 35 U.S.C. § 102(b)

Claims 1-5, 8-10, 12-20, 22-26, 29 and 32-39 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Heinonen. See OA, page 2 ¶ 3.

Applicant notes that claim 10 has been rejected herein, but that the Examiner has indicated that claim 11 (which depends from claim 10) is allowable. Claim 11 has been amended accordingly, and claim 10 has been cancelled without prejudice.

Applicant notes that dependent claim 11, which sets forth allowable subject matter, recites: "wherein positioning said cartridge ... comprises breaking a pressure seal on said cartridge, said breaking adapted to transfer said body fluid to at least one assay

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sensor in said assay sensor module." Applicant notes that this language is also present in allowed claim 21.

With respect to claims 1-5 and 8-9; then, Applicant has amended claim 1 to include such language. Claim 1 already states that the cartridge includes an "interface" with the sampling module (via its sampling port; see lines 5-6) and a passageway adapted "to transport said body fluid to at least one assay sensor in said assay sensor module" (lines 6-7). Thus Applicant has amended claim 1 to further recite "wherein interfacing the cartridge with the sample port includes breaking a pressure seal on the cartridge." Therefore, claim 1 is allowable over Heinonen. Claims 2-5 and 8-9 depend from claim 1 and are therefore allowable for at least the same reasons as in claim 1. Applicant requests that the rejection of claims 1-5 and 8-9 be withdrawn.

In a like fashion, Applicant has amended independent claims 12 (the base claim of dependent claims 13-20), 22, 23 (the base claim of dependent claims 24-26 and 29) and 32 (the base claim of dependent claims 33-39) to include language that recites the subject matter indicated as not being taught or suggested by Heinonen. Thus Applicant respectfully submits that claims 12-20, 22-26, 29 and 32-39 are allowable for at least the reasons set forth above, and accordingly, that the rejection of these claims under 35 U.S.C. § 102 be withdrawn.

# Claim Rejections - 35 U.S.C. § 103(a)

Claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Heinonen. See OA, page 4, ¶ 5. Relatedly, claims 30, 31, 40 and 41 stand

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rejected under 35 U.S.C. § 103(a) as being unpatentable over Heinonen as applied to claims 23 and 32 above, and further in view of Freeman. See Id.

As set forth in the listing of claims and the discussion immediately above, Applicant has amended claims 23 and 32 (the independent claims from which all of these claims rejected under §103 depend) to include claim elements that define over Heinonen, the primary references used in these rejections. Specifically, independent claims 23 and 32 now recite that "a pressure seal on the cartridge is broken, via interface with the analytical detector, during transfer of the body fluid to the assay sensor." Applicant respectfully submits that Heinonen, alone or in combination with either the knowledge of a skilled artisan or Freeman, does not teach or suggest a pressure seal on its cartridge, with breaking of the pressure seal made in conjunction with the transfer of body fluid, as is now recited in all of the claims subject to the instant rejection. Therefore, because their base claims, as amended, recite features that impart patentability over the cited references, Applicant respectfully submits that the rejections to claims 27, 28, 30, 31, 40 and 41 under 35 U.S.C. § 103 be withdrawn.

### Subject Matter Indicated to be Allowable

The Office has indicated that claims 21, 42 and 43 have been allowed, and that claims 6, 7 and 11 would be allowable if rewritten in independent form.

Applicant has rewritten claims 6, 7 and 11 as suggested, and respectfully requests allowance of these claim.

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Allowed claim 21 has been amended regarding antecedent basis; these simple changes, mere typographical corrections made to an *allowed* claim, are obviously made for reasons unrelated to patentability.

## **New Claims**

All of the new claims depend directly or through intermediary claims from claim 21, which was indicated by the Examiner to be allowable. Therefore, Applicant submits that new claims 44-81 are also allowable for at least the same reasons.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 1-9 and 11-81 in condition for allowance.

Again, Applicant submits that the proposed amendments of claims 1, 6, 7, 11, 12, 21-23 and 32 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

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Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims. Furthermore, especially given the application's status in final, the Examiner is urged to contact Andrew B. Schwaab at 650-849-6643<sup>1</sup> if there are any additions/changes Applicant can make to facilitate or expedite allowance of the application.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 50-1078.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: March 19, 2004

Andrew B. Schwaab Reg. No. 38,611

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax Number (703) 872-9306 on March 19, 2004.

Signature:

Andrew B. Schwaab

<sup>&</sup>lt;sup>1</sup> and/or via facsimile as well, at 650-849-6666 (e.g., for advisory actions, etc.).